

1642

DOCKET NO.: L0461.70066US00

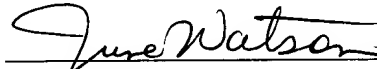
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bernard Lethe, et al.  
Serial No.: 09/341,829  
Confirmation No.: 5643  
Filing Date: October 18, 1999  
For: LAGE-1 TUMOR ASSOCIATED NUCLEIC ACIDS

Examiner: Minh Tam B. Davis  
Art Unit: 1642

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 21<sup>st</sup> day of January, 2004.

  
June Watson

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- ☒ Information Disclosure Statement
- ☒ Form PTO-1449 with References Cited
- ☒ Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617)720-3500, Boston, Massachusetts.

No fee is enclosed. If a fee is necessary, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
**Bernard Lethe et al., Applicants**

By:   
John R. Van Amsterdam, Reg. No. 40,212  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2211  
Telephone: (617) 720-3500

Docket No. L0461.70066US00  
Date: January 21, 2004  
xNDDx



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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**Compliance with 37 C.F.R. § 1.97**

This Information Disclosure Statement has been filed before the mailing date of a first Office Action after the filing of a request for continued examination under 37 C.F.R. §1.114.

No fee or certification is required.

**Information Cited**

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

Explanation of Non-English Language References and Remarks Concerning Other Information Cited

The following is a concise explanation of the relevance of each non-English language reference listed on the attached form PTO-1449 (modified):

The following are remarks concerning the other information cited:

**JP 2002527109T A1 reference corresponds to PCT/EP99/07832 filed October 15, 1999. Translation of claims are provided.**

REMARKS

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

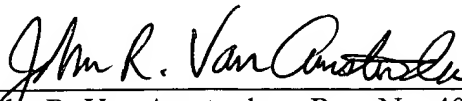
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. § 102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

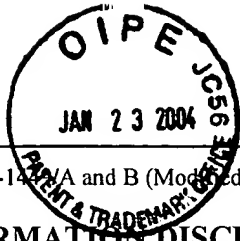
Respectfully submitted,  
*Bernard Lethe et al., Applicants*

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John R. Van Amsterdam, Reg. No. 40,212  
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Date: January 21, 2004

**xNDDx**



<b>FORM PTO-1449A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 09/341,829		ATTY. DOCKET NO.: L0461.70066US00	
				FILING DATE: October 18, 1999		CONFIRMATION NO.: 5643	
				APPLICANT: LETHE et al.			
				GROUP ART UNIT: 1642		EXAMINER: Minh Tam B. Davis	
Sheet	1	of	1				

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials†	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B1	CA	2346942	A1	Boehringer Ingelheim International GmbH	04-27-2000	Y
	B2	EP	1001022	A1	Boehringer Ingelheim International GmbH	05-17-2000	Y
	B3	EP	1121435	A1	Boehringer Ingelheim International GmbH	08-08-2001	Y
	B4	JP	2002527109T	A1	Boehringer Ingelheim International GmbH	08-27-2002	Y
	B5	WO	0023584	A1	Boehringer Ingelheim International GmbH	04-27-2000	Y

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials†	Cite No.	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	SHARMA P. et al., "Frequency of NY-ESO-1 and LAGE-1 expression in bladder cancer and evidence of a new NY-ESO-1 T-cell epitope in a patient with bladder cancer," <i>Cancer Immun.</i> , December 18, 2003; 3:19.	Y
	C2	ODUNSI K. et al., "NY-ESO-1 and LAGE-1 cancer-testis antigens are potential targets for immunotherapy in epithelial ovarian cancer," <i>Cancer Res.</i> , Septemeber 15, 2003; 63(18):6076-83.	Y
	C3	USENER D. et al., "Seroreactivity against MAGE-A and LAGE-1 proteins in melanoma patients," <i>Br J Dermatol.</i> , August 2003; 149(2):282-8.	Y
	C4	SLAGER E.H. et al., "CD4+ Th2 cell recognition of HLA-DR-restricted epitopes derived from CAMEL: a tumor antigen translated in an alternative open reading frame," <i>J Immunol.</i> , February 1, 2003; 170(3):1490-7.	Y
	C5	RIMOLDI D. et al., "Efficient simultaneous presentation of NY-ESO-1/LAGE-1 primary and nonprimary open reading frame-derived CTL epitopes in melanoma," <i>J Immunol.</i> , December 15, 2000; 165(12):7253-61.	Y
	C6	MANDIC M. et al. "The alternative open reading frame of LAGE-1 gives rise to multiple promiscuous HLA-DR-restricted epitopes recognized by T-helper 1-type tumor-reactive CD4+ T cells," <i>Cancer Res.</i> , October 1, 2003; 63(19):6506-15.	Y
	C7	AARNOUDSE C.A., "Interleukin-2-induced, melanoma-specific T cells recognize CAMEL, an unexpected translation product of LAGE-1," <i>Int J Cancer.</i> , July 30, 1999; 30;82(3):442-8.	Y
	C8	LETHE B. et al, "LAGE-1, a new gene with tumor specificity," <i>Int J Cancer.</i> , June 10, 1998; 76(6):903-8.	Y

EXAMINER	DATE CONSIDERED
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†EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_, filed \_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).